

REMARKS

The issues outstanding in the office action mailed June 18, 2002, are the requirement for election/restriction, the objection to claim 22, and the Rejection under 35 U.S.C. §112. No claims are currently rejected over art.

Requirement for Restriction

Applicants' traversal of the requirement for restriction is maintained. As will be recalled, the claims have been divided into four groups:

Group I, claim(s) 1, 2, 4, 5, 8-25, 39, drawn to a method of qualitative and/or quantitative detection of analytes in liquid/solid phases using ferromagnetic or ferrimagnetic substances as labels;

Group II, claim(s) 3, 6, 7, drawn to a method of quantitative and/or qualitative detection of analytes in immunoassays of other binding assays using magnetic field sensors and external magnetic field;

Group III, claim(s) 26, 36-38, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body; and

Group IV, claim(s) 27-31, 35, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body using external magnetic field and magnetic field sensors.

First, it is submitted that all four groups of claims employ the "same or corresponding special technical feature", that is, the use of ferrimagnetic or ferromagnetic substances as labels to detect substances in a homogeneous immunoassay, without the need to separate unbound magnetic markers. While the current office actions argues, at page 2, that the "special technical features that the applicants define are well known in the art", this is contrary to the indication at page 5 of the office action that the "prior arts [sic] do not teach a method of qualitative and/or

quantitative detection of analytes in a liquid and/or solid phase homogeneous assay, comprising determining the remanence magnetization in said homogeneous assay after addition to a sample of a stable or a quasi-stable ferromagnetic or ferromagnetic [sic, ferromagnetic] substances." Indeed, the lack of an art rejection suggests that all claims do, in fact, possess the same technical feature responsible for patentability and, thus, that the restriction requirement should be withdrawn.

Second, the restriction requirement is internally inconsistent in a manner which clearly shows the artificiality of the groups into which the claims have been divided. For example, the restriction seems to suggest that the difference between group I and group II, or between group III and group IV, is the use of magnetic field sensors and external magnetic fields. However, it is submitted that the use of an external magnetic field is needed in order to practice the invention. The examiner has offered no explanation as to how the invention can be conducted without the external magnetic field; thus, the claims in groups I and groups III in essence require all of the elements of groups II and groups IV and vice versa. It is submitted that the requisite distinctness to support a restriction requirement, accordingly cannot be shown. Moreover, under the PCT rules, e.g., 37 CFR §1.475, the groups of the invention set forth in the requirement for restriction thus do not contain different special patentable features. The restriction requirement must therefore be withdrawn.

Claim Objection

Claim 22 has been objected to, as it depends on non-elected claim 3. This claim further demonstrates the inconsistency in the restriction requirement. Claim 22 recites various particular structure-specific substances. Thus, the claim is a little different from elected claims 4

and 5. However, this claim depends upon claim 3 which is alleged to require an external magnetic field, thus in non-elected group II. As such, this claim also requires an external magnetic field and, accordingly, if it is in the elected group, the claim upon which it depends, claim 3, should also be in the elected group. In any event, the requirement for restriction should be withdrawn.

Rejections under 35 U.S.C. §112

Claims 1, 2, 4, 5, 8-18, 22-25 and 39 have been rejected under 35 U.S.C. §112, second paragraph. The examiner's careful reading of these claims is appreciated. Various typographical and grammatical changes have been made to the claims, which changes do not change the scope of these claims either literally or for purposes of the doctrine of equivalents.

In addition, the various comments concerning claims 8 are not understood. Page 4 of the office action queries how the sample is "moved" in accordance with claim 8. It is believed that its evident that physical movement is intended; for example, at page 8, it is indicated that the signal can be modulated by moving, e.g., by vibration or rotation of the sample. Thus, the claim is believed clear on its face.

Moreover, with respect to the query concerning claim 11, in this claim multiple samples are measured. The claim has been clarified.

Finally, with respect to claim 4 and 5, it is argued in the office action that it is confusing, "whether the samples contain analytes." In fact, as believed evident from the specification, there are in essence two alternatives set forth for performing the process. The substrate-specific substances may be labeled with the magnetic substances, and subsequently added to the analytes.

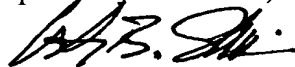
Alternatively, the analytes may be labeled with the magnetic substances, and subsequently a structure-specific substance added. See, for example, page 6 of the specification.

Accordingly, it is submitted that the claims fully satisfy the requirements of the second paragraph of this section of the statute. Withdrawal of the rejection is respectfully requested.

In conclusion, the claims in the application are submitted to be in condition for allowance. However, should the examiner have any questions or comments, she is cordially invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Four Times Amended) A process for qualitative and/or quantitative detection of analytes in a liquid and/or solid phase homogeneous immunoassay, comprising determining remanence magnetization in said homogeneous immunoassay ~~after addition to a sample~~ of a stable or quasi-stable ferromagnetic or ferrimagnetic ~~substances~~ substance bound to said analyte.

2. (Thrice Amended) A process for qualitative and/or quantitative detection of analytes in homogeneous immunoassays comprising measuring remanent magnetization of ~~bound~~ magnetic markers in a sample, bound to said analytes, wherein at the time of measurement the magnetization of unbound magnetic markers that are present in the sample in their totality fades owing to extrinsic superparamagnetism.

5. (Thrice Amended) A process according to claim ~~1~~ 40, wherein the structure-specific substances are antibodies, antibody fragments, biotin, substances that bind specifically to biotin, agonists that bind specifically to receptors of their antagonists, peptides, proteins, receptors, enzyme substrates, nucleotides, ribonucleic acids, deoxyribonucleic acids, carbohydrates, or lipoproteins.

11. (Twice Amended) A process according to claim 1, wherein simultaneous determination of several different analytes in a sample of liquids or solid substances is carried out by sequential magnetization of a sample to be measured.

35. (Thrice Amended) The process according to claim 27, wherein a mixture of different ferrimagnetic or ferromagnetic substance with structure-specific substance ~~issued~~ is used.